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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,528	06/14/2000	Kent A. Louviere	298.006	7692

7590

08/20/2002

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EXAMINER

STAICOVICI, STEFAN

ART UNIT

PAPER NUMBER

1732

DATE MAILED: 08/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/594,528

Applicant(s)

LOUVIERE, KENT A.

Examiner

Stefan Staicovici

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7 and 16 is/are rejected.
- 7) ☒ Claim(s) 2-5,8-15 and 17-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Method of Making a Plurality of Interconnected Vials."
2. The abstract of the disclosure is objected to because the abstract should be a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. It is suggested to include the steps of filling the molded interconnected vials and sealing said filled interconnected vials. Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following informalities:
 - on page 10, line 7, "FIGURE 2" should be replaced with --FIGURE 2A and 2B--;
 - on page 13, line 3, after "output", "?" should be deleted;
 - on page 13, lines 4-5, "34" should be replaced with --44—and, "36" should be replaced with --42-- in order to conform to Figure 1;
 - on page 20, line 1, it is unclear whether Applicant is referring to Figure 5 A or 5B;
 - on page 23, line 16, after "used", --as-- should be inserted
 - on page 25, lines 13-14, it is unclear why the sentence beginning with ",Both..." and ending with "...heat sealing" has been written in bold typeface.

Appropriate correction is required.

Drawings

4. The drawings are objected to because the label "Figure 2" should be deleted since the original specifications refers only to Figures 2A and 2B. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 6-7 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,101,791 in view of Porfano *et al.* (US Patent No. 6,164,044).

U.S. Patent No. 6,101,791 teaches the basic claimed process for manufacturing a plurality of interconnected vials including, providing a mold having a first member having a first end with an opening defined within said first end and, a second end; a manifold member operatively attached to said second end of said first member for channeling a plastic fluid to a first slide and

a second slide positioned within the opening, with said first slide and second slide having an extended position and a contracted position, and a means for extending said first slide and said second slide to the extended position; a second member having a first end and a second end, and wherein said first end of said second member contains a plurality of core pins contained therein; an ejector plate selectively attachable to said second member, said plurality of core pins being disposed therethrough; and, a piston adapted to said second end of said second member for reciprocating said second member into engagement with said first slide and said second slide. Further, U.S. Patent No. 6,101,791 teaches heating a plastic so that the plastic fluid is formed, channeling the plastic fluid into the manifold, heating the plastic fluid within said manifold, injecting the plastic fluid through said first member and into said first slide and said second slide, moving said piston so that said second member contacts said first slide and said second slide, contracting said first slide and said second slide so that said contracted first slide and said second slide form a plurality of cavity profiles and wherein said plurality of cavities are linked together by a plurality of arms, said cavity profiles having a first end and a second end, with the first end containing a wing tip contour, and the second end being opened, placing said plurality of core pins into said plurality of cavity profiles and wherein said plurality of core pins are in a free standing arrangement within said cavity profiles, injecting the plastic fluid into said cavity profiles, injecting the plastic fluid about said plurality of core pins so that the plasticized fluid is disposed about said core pin so that the plurality of interconnected medical vials are formed, reciprocating the piston away from the first end of said first member, allowing the first slide and second slide to expand, reciprocating the piston so that the ejector plate axially traverses the

plurality of core pins, ejecting the plurality of interconnected medical vials from the plurality of core pins and wherein said plurality of interconnected medical vials contains a winged tip extension on the first end and a cylindrical outer diameter on the second end. Furthermore, U.S. Patent No. 6,101,791 teaches providing a drug in a liquid embodiment, inserting the liquid into the open end of said molded plurality of interconnected medical vials, heat sealing the open end so that the plurality of interconnected medical vials are a plurality of closed (encapsulated) containers.

Regarding claims 1, 6 and 16, US Patent No. 6,101,791 does not teach placing said interconnected vials within a vial holder tray. Porfano *et al.* ('044) teach a process for assembling and packaging a plurality of medical plastic vials (col. 4, lines 50-60) including, positioning said vials prior to packaging in a tray (84) (see Figure 5). Therefore, it would have been obvious for one of ordinary skill to have provided a tray as taught by Porfano *et al.* ('044) to hold a plurality of interconnected vials in the process of US Patent No. 6,101,791 because, Porfano *et al.* ('044) specifically teach the use of a tray for holding a plurality of plastic vials prior to packaging and sealing said vials whereas, US Patent No. 6,101,791 teach molding and ejecting a plurality of plastic medical vials and further, filling and sealing said molded plastic medical vials and also because, both references teach similar materials and end-products.

Allowable Subject Matter

7. Claims 2-5, 8-15 and 17-19 would be allowable if rewritten to overcome the Double Patenting rejection(s) as set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method for molding a plurality of interconnected vials including, providing a plurality of core pins and an insert means containing a first slide and a second slide having an extended and a contracted position, contracting said first slide and second slide to form a plurality of cavity profiles linked together by a plurality of arms, positioning said cores into said plurality of cavity profiles so that said plurality of core pins are free standing within said plurality of cavity profiles and injecting a plastic fluid about said plurality of core pins to form a plurality of interconnected vials.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-0396. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H. Silbaugh, can be reached at (703) 308-3829. The fax phone number for this Group is (703) 305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Stefan Staicovici, PhD

A handwritten signature in black ink, appearing to read 'Stefan Staicovici', written over a horizontal line.

AU 1732

8/18/02

SS

August 18, 2002